APR 20 2010 K100618 (1/2)

# 510(K) Summary of Safety and Effectiveness

## MaxLock Extreme® Extremity Plating System with Variable AngleTechnology

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| **Proprietary Name:** | MaxLock Extreme® Extremity Plating System with Variable Angle Technology |
| **Common Name:** | Bone Fixation Screws |
| **Classification Name and Reference:** | 888.3030 - Single/multiple component metallic bone fixation appliances and accessories |
| **Regulatory Class:** | Class II |
| **Device Product Code:** | HRS - Single/multiple component metallic bone fixation appliances and accessories |
| **Contact Information:** | Derek Lewis<br>Vice-President of Research and Development<br>OrthoHelix Surgical Designs Inc.<br>1065 Medina Rd., Suite 500<br>Medina, OH 44256<br>Phone: 330 869-9562<br>Fax: 330 247-1598<br>E-Mail: dlewis@orthohelix.com |
| **Summary Date:** | April 15, 2010 |

**Device Description**

This special 510(K) submission is a modification to the previously cleared Modular Foot and Clavicle systems to add a variable angle locking screw construct. No changes have been made to the current locking plates; this addition will be compatible with all plates currently in the system. The OrthoHelix variable angle construct consists of a polymer ring which mates with the locking plate and allows for a specially designed locking screw to be inserted at angles up to 15° in any direction while maintaining angular stability.

**Intended Use**

Variable Angle technology in MTP, TMT, MFT, MXL, DFX, and EDL plates are indicated for fractures, fusions and osteotomies for small bones in the hand, wrist, foot and ankle in both pediatric and adult patients.

Variable Angle Technology in MXL and CLA plates are indicated for the fractures, fusions, and osteotomies of the clavicle and small bones in the hand, wrist, foot and ankle.

**Substantial Equivalence**

The MaxLock Extreme® Extremity Plating System with Variable Angle Technology is substantially equivalent to currently marketed devices, the OrthoHelix Modular Foot System (K073624) and Clavicle Plating System (K090289) and the Stryker VariAx System (K060613). The new technology is a modification to the OrthoHelix Modular Foot System, K073624 and Clavicle Plating System, K090289. The new technology only differs from the predicate devices with inclusion of a polymer locking ring and a specially designed locking screw to facilitate a variable angle locking mechanism.

Dynamic and static mechanical testing confirm that the MaxLock Extreme® implants with Variable Angle Technology are substantially equivalent to their predicate and meet the specified requirements for their intended use. No new issues of safety and efficacy have been raised during the development of this system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OrthoHelix Surgical Designs, Inc.
% Mr. Derek Lewis
Vice President of Research and Development
1065 Medina Road, Suite 500
Medina, Ohio 44256

APR 20 2010

Re: K100618
Trade/Device Name: MaxLock Extreme® Extremity Plating System with Variable Angle Technology
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: April 5, 2010
Received: April 6, 2010

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buehrer

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): ~~TBD~~ K100618

Device Name: MaxLock Extreme® Extremity Plating System with Variable Angle Technology

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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